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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	06/09/98	NYCE	J	[illegible]

HM12/0918

VIVIANA AMZEL, PH.D.
EPIGENESIS PHARMACEUTICALS, INC.
7 CLARKE DRIVE
CRANBURY NJ 08512

EXAMINER	
EPPS, J	
ART UNIT	PAPER NUMBER
1635	13

DATE MAILED: 09/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Advisory Action

Application No.	Applicant(s)	
09/093,972	NYCE, JONATHAN W.	
Examiner	**Art Unit**	
Janet L Epps	1635	

--Th MAILING DATE of this communication appears on the cover sh et with the correspondence address --

THE REPLY FILED 21 August 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *04 May 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *108-131,133,134,146,148,151-156,158,159,161-173,178-181,184-189,191-193,195-198 and 200-234 for the reasons of record in the Final Office Action*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 2. NOTE: Applicant's amendment to claims 115, 117, 124-125 and 231 have broadened the scope of these claims therefore requiring further consideration and/or search. The amendment to claim 171 raises the issue of new matter, Applicants have amended claim 171 to change ref r to a nucleic acid a particle size of about .5 u to about 10 u or about 10u to about 500 u, the original claim referred to a powdred or liquid aerosol formulation for delivering nucleic acid comprising a particle size of about .5 u to about 10 u or about 10u to about 500 u.

Continuation of 10. Other: See attached note.

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 200 is amended to recite [(b) obtaining a first oligo 4 to 60 nucleotides long which comprises the selected fragment and has a C and G nucleic acid content of up to and including about 15%; and (c)]. This amendment does not comply with 37 CFR 1.121 since there is underlining and bracketing within a set of brackets. It is unclear what exactly applicants are attempting to amend. See the notice of non-compliant amendment mailed 7-23-01.

3. On page 1 of the Amendment filed 8-21-01, Applicants request that the Sequence Listing filed May 4, 2000 be disregarded and replaced with the one filed March 22, 2001. This request by Applicants is unclear since Applicants have provided another Sequence Amendment on April 5, 2001. Additionally, on page 3 of the Amendment filed 8-21-01, applicants state: "A Substitute Sequence Listing and a Declaration have been provided to the examiner who is requested to substitute it for that filed May 4, 2000." This request again is unclear since the instant amendment does not include an attachment comprising a Substitute Sequence Listing and a Declaration.

4. Claims 108-131, 133-134, 146, 148, 151-156, 158-159, 161-173, 178-181, 184-189, 191-193, 195-198, and 200-234 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using pharmaceutical compositions comprising antisense oligonucleotides targeting adenosine receptor mRNA effective in treating an asthmatic condition provoked by the administration of

adenosine, does not reasonably provide enablement for the treatment of allergies or inflammation broadly, or for using pharmaceutical compositions comprising antisense targeting any other mRNA target other than adenosine receptor mRNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons of record set forth in the Official Action mailed 11-07-2000.

Since Applicants have not provided any arguments or amendments which would overcome this rejection, the instant claims remain rejected for the reasons of record.

As stated in the Official Action mailed 11-07-2000, the specification as filed fails to provide an enabling disclosure that would teach one of skill in the art how to treat inflammation, and allergies broadly, by the administration of a pharmaceutical composition comprising an antisense oligonucleotide targeting adenosine receptor mRNA or any other mRNA target. The specification as filed does not enable anyone of skill in the art to practice the instant invention throughout the full scope of the claimed invention. This conclusion is based upon the known unpredictability in the art regarding antisense based therapeutics, the lack of guidance, direction or description provided by the specification, the limited number of working examples provided by the specification, the breadth of the claims, and the amount of experimentation need to practice the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

JLE
September 17, 2001

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600